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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,100

09/10/2003

Paul Albert Sagel

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THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/659,100	Applicant(s) SAGEL ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-10 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-10 and 19-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed November 26, 2008 with the Request for Continued Examination, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 112 – New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-10, 19-22 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the limitation “wherein the plurality of void spaces extends through the thickness of the film”. The instant specification recites “In a related embodiment, a perforated film without a distinct

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web or scrim might be provided, as shown in FIG. 7. In the tooth whitening product 620, a single or multilayer film might be provided comprising a water hydratable polymer, a tooth whitening agent, and a plasticizer. The film can be perforated after it has dried or cured. The void spaces, holes, or apertures 630 that are formed during the perforation process can pass completely through the thickness of the film or might only partially penetrate the film thickness” (paragraph 0026 of the published application). The limitation does not appear to be supported by the originally filed application because the recitation of the holes completely passing through the film is in regards to a film without mesh. This limitation in the instant claims relate to a film with a scrim. Therefore it appears the limitation is “New Matter”.

Claim Rejections - 35 USC § 102 – Anticipation (Previous Rejection)

Claims 8-10, 19, 20, 22, and 28-32 were rejected under 35 U.S.C. 102(e) as being anticipated by Willison et al. (US 2004/0005277). The rejection is maintained in regards to claims 28-31 and withdrawn in regards to claims 8-10, 19, 20 and 22.

Applicant's Arguments

Applicant argues in regards to instantly rejected claim 28 that neither of the characterizations by Willison et al anticipates where void spaces extend from the first side of the mesh to the second side of the mesh because the oral care layer surrounds the scrim. This argument is not persuasive.

Examiner's Response

The reference discloses a scrim (a mesh), which is surrounded by an oral care layer meeting the limitation of a coating. The actual fibers that are coated do create void spaces in the mesh and therefore meet the limitation the coated fibers provide a plurality of void spaces that extend from the first side of the mesh to the second side of the mesh. The claim does not specify that the void spaces could not be filled with the oral care layer. Therefore the rejection is maintained.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)

Claims 21 and 23-27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Willison et al. (US 2004/0005277) as applied to claims 8-10, 19, 20, 22 and 28-32 above in view Chen et al. (US 6,261,679). The rejection is maintained in regards to claims 23-27. The rejection is withdrawn in regards to claim 21 and 24.

Applicant's Arguments

Applicant argues all the articles in Chen are designed to absorb and retain fluids whereas Applicant's invention is directed to tooth whitening products. While the mesh of the instant claims comprises a water hydratable polymer, it is not generally an absorbent article as discussed in Chen, but instead a part of the product used to deliver the tooth whitening agent. Further the reference is not enabling for making a tooth whitening product. This argument is not persuasive.

Examiner's Response

Chen discloses the materials may be used as dental absorbents or saliva absorbents (col. 2, lines 55-59), Therefore making them suitable for use in a dental product. Willison et al. discloses the adhesive properties of the oral care layer with respect to bonding to the teeth are enhanced by hydration, for example with water or saliva. One of ordinary skill in the art would be motivated to use the fibers of Chen because they would aid in the adhesive properties of oral care layer by absorbing water or saliva. In regards to the reference not being enabling, Chen discloses how to make the fiber materials and it would take no more than relative skill in the art to incorporate these materials into the procedures disclosed by Willison to make the final whitening product.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claims 8-10, 19, 20 and 22-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leaderman (2002/0061329).

Leaderman discloses system that may be used to deliver whitening agents to teeth. The dressing can be constructed in the form of a sponge or sheet impregnated with the gel, and may contain a tooth-whitener (see Abstract). The backing may be a porous substrate that has air holes and allows the covered area to breath and dry, thus maintaining or increasing the adhesiveness (paragraph 0021). Polymers used in the aqueous gels include vinyl polymers such as polyvinyl pyrrolidone,

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poly(ethylene)oxides, acrylamide polymers and derivatives and salts thereof, encompassing claims 8, 25 and 26. It is also to be understood that poly(ethylene)oxides includes polyethylene glycol (paragraphs 0027 and 0028). The gel, foam and/or film formulations in accordance with the preferred embodiments of the invention can be used to coat fibers of an absorbent gauze dressing, nonporous, porous, or micro porous fabric and provide dressings that can be placed in the oral cavity. The gels, foams or film formulations can be applied to the dressing material by soaking, spray coating or dip coating (paragraph 0039). The dressing materials include porous, non porous, or micro porous polyesters, rayons, cottons, wools, silks, papers, foams (open and closed cell), woven and non-woven fabrics, polyolefins, polyesters, copolyesters, polyurethanes, ethyl vinyl acetate, polyether block amides, ethylene methacrylic acids or polyethylene (paragraph 0041), encompassing claims 10 and 22.

The non-woven and woven fabrics are interpreted as the mesh of the instant claims. The gels are applied by soaking, spray coating or dip coating, which encompasses that the void spaces extends through the thickness of the film and partially fills the mesh. This is also considered as coating the fibers of the fabric.

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables a

whitening agent, film, a mesh and coating the mesh with the film in such a way to the void spaces extend through the thickness of the film, anticipation cannot be found.

That being said, however, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients such as a whitening agent, a woven or non-woven fabric, a spray coating of the gel, from within a prior art disclosure, to arrive compositions “yielding no more than one would expect from such an arrangement”.

2) Claims 10, 19, 20, 22-24, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (US 2005/0260544).

Jones et al. disclose delivery systems for delivering oral healthcare substances to the teeth. A preferred device is a device comprising a strip with an absorbent material with a peroxide-containing tooth whitening gel. The gel may comprise a gelling agent, which include water hydratable polymers, (paragraph 0035) and carriers such as polyethylene glycol (paragraph 0037) and water (paragraph 0036). The absorbent material includes a fabric, woven or non-woven material. The fabric comprises polypropylene, viscose or a polypropylene-viscose blend (paragraph 0015), encompassing claim 10. The whitening gel may be impregnated into the absorbent's material's bulk. Methods of depositing the oral care materials onto the strips include spraying and dipping. The gel can soak into the adsorbent material and can be completely absorbed by the material, or some may remain unabsorbed as a surface layer. It is found that the absorbent fabric helps to retain the substance on the device (paragraph 0048) The oral care layer may also be in the form of a perforated layer (paragraph 0070).

The non-woven and woven fabrics are interpreted as the mesh of the instant claims. The gels are impregnated or absorbed into the material, which encompasses that the void spaces extends through the thickness of the film and partially fills the mesh. This is also considered coating the fibers of the fabric.

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several

variables does not necessarily give rise to anticipation. Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables such as a whitening agent, non-woven or woven fabrics as a mesh, and method of applying the oral care compositions to the mesh, anticipation cannot be found.

That being said, however, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients of a whitening agent, a woven or non-woven fabric and absorbing the oral care composition onto the fabric, from within a

prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement".

3) Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (US 2005/0260544) in view of Ruben (US 6,146,655).

Jones et al. is discussed above. The reference differs from the instant claims insofar as they do not disclose the diameter of the fibers comprised in the fabric.

Ruben discloses oral bandages and drug delivery systems. The systems are gel/fiber compositions wherein the fiber is used as reinforcement to the gel. The fibers have an individual length of at least 3 mm, and preferably in the range of from about 2 mm to about 4 mm, to obtain the desired reinforcement effect. There should be at least one order of magnitude difference between the diameter and length of the fibers (col. 3, lines 35-45). It is concluded the fibers will have a diameter of at the 200 microns when the length of the fibers is 2 mm. After the kit is removed from the liquid, the tacky fiber-reinforced gel is removed from the package and envelope, and manually molded and positioned in place over a desired tissue surface in a patient's oral cavity. The fiber may be made of natural cellulosic fibers or synthetic fibers (col. 4, lines 53-65). The reference differs from the instant claims insofar as it does not teach the fibers form a mesh and the compositions include a tooth-whitening agent.

It would have been obvious to one of ordinary skill in the art to have used fabrics with fibers with certain dimensions as fabrics of the primary reference motivated by the desire to use material that would reinforce the gel compositions with the desired

reinforcement effect when wet and placed in the mouth as taught by the secondary reference.

4) Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (US 2005/0260544) in view Chen et al. (US 6,261,679).

Jones et al. is discussed above. The reference differs from the instant claims insofar as they do not disclose the fibers of the fabric comprise a hydratable polymer although it teaches the fibers are coated with a hydratable polymer

Chen et al. disclose hydrophilic fibers are used to make structures with good integrity and resiliency (col. 1, lines 50-55). Fiber enforced foams usually comprise hydrophobic fibers and lack high-bulk, absorbent attributes desired on an absorbent article. The structures of the reference comprise hydrophilic fibers to remedy this problem (col. 1, lines 17-39). The structures may be used as dental absorbents and medical sponges (col. 2, lines 42-60). The reference differs from the instant claims insofar as it does not disclose the structures comprise oral care agents such as whitening agents.

It would have been obvious to one of ordinary skill in the art to have used hydrophilic fibers as the absorbent fabric for the devices of Jones et al. motivated by the desire to increase the integrity and resiliency of the device without subtracting from absorbent attributes desired in an absorbent material, as disclosed by Chen et al.

Claims 7-10 and 19-31 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
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/Frederick Krass/

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